

extends in width to the inner surface of the sheath, but that Deem shows such a device.

Claim 13 recites an apparatus for facilitating insertion of a flexible medical device into a body lumen comprising an elongated body portion and a valve including foam material filling at least some of the length of a passageway of the elongated body portion. A length of the foam material is greater than a width of the foam material at any point and the valve includes a plurality of self-sealing slits wherein none of the slits extends in width to an inner surface of the sheath.

It is respectfully submitted that Deem includes no disclosure of such a valve with slits that do not extend to an inner surface of the sheath as contended by the Examiner. Rather the slits in one embodiment are described as not extending all the way through the valve (partition member 24) longitudinally. There is no reference to the extent of the slits in the transverse direction. Specifically, col. 6, lines 1 - 7 of the specification state that Figs. 3 and 4 show opposed sides of a partition member 24 where slit 40 does not extend all the way therethrough. However, it is respectfully submitted that Figs. 3 and 4 show proximal and distal end views of the partition member 24, respectively, with the distal end view of Fig. 4 showing no slits on its surface whatsoever. Thus, it is submitted that this reference is only to the extent of the slits in a longitudinal direction. This is made clear by the statement in lines 4 - 5 of col. 6 that the slits 40 of this embodiment are useful to start penetration of an elongated member where the elongated member is capable of penetrating the foamed material without use of a slit. it is further submitted that the drawings are not made to scale and, with no supporting description, Deem cannot be said to show

or suggest slits that do not extend radially to an inner surface of the sheath.

In addition, there is ample legal authority for the proposition that the prior art must suggest the desirability of doing what an applicant has done. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1271, 20 U.S.P.Q. 2d 1746, 1751 (Fed. Cir. 1991) and it is improper, therefore, to engage in a hindsight reconstruction of a claimed invention using an applicant's disclosure as a template and selecting elements from the prior art to fill the gaps. In re Gorman, 933 F.2d 982, 987, 18 U.S.P.Q. 2d 1885, 1888 (Fed. Cir. 1991). Put another way, *it is improper to modify a prior art reference unless the prior art suggests the desirability of the specific modification.* In re Gordon, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). The suggestion for making an applicant's combination must come from the prior art, Carella v. Starlight Archery and Pro Line Co., 804 F.2d 135, 140, 231 U.S.P.Q. 644, 647 (Fed. Cir. 1986), and not from applicant's specification. In re Vaeck, 947 F.2d 488, 493, 20 U.S.P.Q. 2d 1438, 1442 (Fed. Cir. 1991). There must be some reason for the combination other than hindsight gleaned from applicant's specification. Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985).

It is respectfully submitted that all of the embodiments of Walker are shown with at least one slit that does extend through the entire width of the foam valve because this feature aids in the splitting of the sheath and its removal from the catheter while leaving the catheter in place within the body. Therefore, it is respectfully submitted that neither reference shows any motivation for making the combination suggested by the

Examiner and that this rejection should be withdrawn.

Specifically, Walker describes a sealing structure 30 which is adapted to be split through to the central opening 32. "This can be accomplished by an actual split through to the periphery 34 or by having a weakened portion which can be readily split through by the user." (Specification, col. 5, lines 47 - 49).

In addition, it is respectfully submitted that Walker neither shows nor suggests foam material having a length greater than a width of the foam material at any point. Fig. 9 is described as showing a sealing structure 30D which is similar to that of Fig. 6 but which is considerably longer longitudinally. (Specification, col. 7, lines 38 - 44). However, Walker includes no description of this longitudinal length to the width of the sealing structure 30D. It is respectfully submitted that the drawings cannot be relied on for dimensions and proportions and that, therefore, Fig. 9 and its corresponding description are not sufficient to establish any relationship between the length and width of the sealing structure 30D. M.P.E.P. § 2125. It is further suggested that Deem also fails to describe or suggest any particular relationship between the width and length of the partition 24. Deem states only that the partition member 24 typically has a thickness of 0.001 inch and states that the drawings show this structure thicker than this for purposes of illustration. (Specification, col. 4, lines 62 - 68).

Thus it is respectfully submitted that neither Walkner nor Deem shows or suggests an apparatus for facilitating insertion of a flexible medical device into a body comprising an elongated body portion with a passageway therethrough and a valve comprising "foam material filling at least some of the length of the passageway. . . , the length of the foam material within the

passageway being greater than the width of the foam material at any point within the passageway," as recited in claims 13, 26 and 39.

For these reasons it is respectfully submitted that claims 13, 26 and 39 are not rendered obvious by Walker and Deem either taken alone or in combination and that this rejection should be withdrawn. Because claims 12, 14 - 23, 25, 27 - 34, 36 - 38 and 40 - 45 depend from and, therefore, include all of the limitations of one of claims 13, 26 and 39, it is submitted that these claims are also allowable.

Furthermore, it is respectfully submitted that the combination of Walker and Deem is not supported by any motivation provided within either of these references and that this combination of references should no longer be applied.

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

Dated: July 17, 2003

By: 

Patrick J. Fay
Reg. No. 35,508

Fay Kaplun & Marcin, LLP
150 Broadway, Suite 702
New York, New York 10038
Tel: (212) 212-619-6000
Fax: (212) 208-6819